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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,938	07/25/2006	Sven Klussmann	14167-00002-US	2223

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CONNOLLY BOVE LODGE & HUTZ, LLP
P O BOX 2207
WILMINGTON, DE 19899

EXAMINER	
PANDE, SUCHIRA	
ART UNIT	PAPER NUMBER
1637	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,938	KLUSSMANN ET AL.	
	Examiner	Art Unit	
	SUCHIRA PANDE	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-78* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of group I invention (claims 1-30) in the reply filed on April 9, 2008 is acknowledged. Applicant has also elected following species:

Category a - Species of nucleic acid: option vii - wherein the nucleic acid has a secondary structure shown in Figure 1B. Claims 1 and 9 read on the elected species.

Category b - Species of interaction partners: option xxiv - wherein the interaction partner is nucleic acids. Claim 35, 36, 38, 39, 51 and 54 read on the elected species.

Category c - Species of ghrelin: option xxviii - bioactive ghrelin. Claims 31, 45, 46, 47, 50, 52, 56 and 73 read on the elected species.

Category d - Species of functional nucleic acid: option xxxi - spiegelmers. Claims 54 and 55 read on the elected species.

Category e - Species of detection means: option xxxii - detection means is a nucleic acid. Claims 57 and 58 read on the elected species.

Category f- Species of detection label: option xxxviii - detection label is biotin. Claims 32, 63, 64 and 66 read on the elected species.

Category g - Species of second detection means: option li - a streptavidin carrying molecule. Claims 65 and 66 read on the elected species.

Use claims 13-30 were grouped with the product claims in the restriction requirement mailed on November 9, 2007. This is incorrect as use claims are method claims. Hence only claims 1-12 properly belong to group I invention drawn to a product. Claims 13-30 drawn to use claims need to be grouped as part of method claims. A closer scrutiny of the method claims indicates that these use claims comprise several

distinct inventions. Under the circumstances more than 50% of the claims (13-30) from the elected invention namely product based on the restriction mailed on November 9, 2007 fall into the non-elected invention category namely method.

For purposes of clarifying the record, a new restriction requirement showing various groups and species election is being mailed. Should the Applicant choose to pursue prosecution of product claims as per the election filed on April 9, 2008; then examination will be restricted to claims 1, 5-6, and 9 that are commensurate with the elections made above.

Examiner would like to point out that as no substantive examination has been done, in response to this new restriction requirement that is being mailed, Applicant is free to choose any other group for examination.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12, drawn to a product namely nucleic acid which binds to bioactive ghrelin.

Group II, claim(s) 13-21, 31-78, drawn to use and method for detecting bioactive ghrelin by binding nucleic acid.

Group III, claim(s) 22-26 drawn to use of nucleic acid for inhibition of bioactive ghrelin.

Group IV, claim(s) 27 drawn to use of nucleic acid for manufacture of a medicament. Group V, claim (s) 28-30 drawn to use of a medicament for treatment and/ or prevention of a disease.

3. The inventions listed as Groups I through V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Bednarek et al. (2000) J. Med. Chem. 43:4370-4376 (previously provided to Applicant) teaches a nucleic acid which binds to a bioactive ghrelin. See whole article especially page 4371 par. 2 where bioactive ghrelin is taught and see par. 3 where binding of human ghrelin to cloned hGHSRI (nucleic acid) is taught. Thus a nucleic acid which binds to a bioactive ghrelin was taught by prior art at the time the invention was made. Hence invention of Group I (product) does not share the same special technical feature as invention of groups II-V (methods). Hence unity of invention is lacking.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Group I invention

a. Species of the type of nucleic acid (claim 1 is generic)

i. wherein the nucleic acid is a L-nucleic acid (claim 7)

ii. wherein the nucleic acid is deoxyribonucleic acid (claim 8 in part)

iii. wherein the nucleic acid is ribonucleic acid (claim 8 in part).

iv. wherein the nucleic acid is mixture of deoxyribonucleic acid and ribonucleic acid (claim 8 in part).

b. Species of nucleic acid based on structure (claim 1 is generic)

v. wherein the nucleic acid has a secondary structure shown in Fig. 1B (claim 9).

vi. wherein the nucleic acid is variable in the internal loop structure of the secondary structure shown in Fig. 1B (claim 10).

vii. wherein the nucleic acid comprises, a sequence according to SEQ. ID. No 1 (claim 11).

viii. wherein the nucleic acid comprises, a sequence according to SEQ. ID. No. 2 (claim 12 in part)

ix. wherein the nucleic acid comprises, a sequence according to SEQ. ID. No. 3 (claim 12 in part)

x. wherein the nucleic acid comprises, a sequence according to SEQ. ID. No. 4 (claim 12 in part)

xi. wherein the nucleic acid comprises, a sequence according to SEQ. ID. No. 5 (claim 12 in part)

xii. wherein the nucleic acid comprises, a sequence according to SEQ. ID. No. 6 (claim 12 in part)

xiii. wherein the nucleic acid comprises, a sequence according to SEQ. ID. No. 7 (claim 12 in part)

xiv. wherein the nucleic acid comprises, a sequence according to SEQ. ID. No. 8 (claim 12 in part)

xv. wherein the nucleic acid comprises, a sequence according to SEQ. ID. No. 9 (claim 12 in part)

xvi. wherein the nucleic acid comprises, a sequence according to SEQ. ID. No. 10 (claim 12 in part)

xvii. wherein the nucleic acid comprises, a sequence according to SEQ. ID. No. 11 (claim 12 in part)

xviii. wherein the nucleic acid comprises, a sequence according to SEQ. ID. No. 12 (claim 12 in part)

xix. wherein the nucleic acid comprises, a sequence according to SEQ. ID. No. 13 (claim 12 in part)

xx. wherein the nucleic acid comprises, a sequence according to SEQ. ID. No. 14 (claim 12 in part)

xxi. wherein the nucleic acid comprises, a sequence according to SEQ. ID. No. 15 (claim 12 in part)

c. Species of nucleic acid based on binding to ghrelin (claim 1 is generic)

xxii. The nucleic acid which specifically binds to a bioactive ghrelin (claims 2, 4).

xxiii. the nucleic acid does not specifically bind to a bioactive ghrelin (claim 3).

Group II invention

d. Species of interaction partners (claim 35 is generic)

xxiv. interaction partner is nucleic acids (claims 36 in part, 38, 39, 51 in part, 54)

xxv. interaction partner is polypeptides (claim 36 in part, 51 in part)

xxvi. interaction partner is proteins (claim 36 in part, 51 in part)

xxvii. interaction partner is antibodies (claims 36 in part, 37, 51 in part, 53)

e. Species of ghrelin

xxviii. Bioactive ghrelin (claims 31, 45, 46, 47 in part, 50 in part, 52 in part, 56 in part, 73)

xxix. Non-bioactive ghrelin (claims 47 in part, 50 in part, 52 in part, 56 in part, claim 74)

f. Species of functional nucleic acid (claim 54 is generic)

xxx. Aptamers (claim 55 in part)

xxxi. Spiegelmers (claim 55 in part)

g. Species of detection means (claim 57 is generic)

xxxii. Detection means is a nucleic acid (claim 58)

xxxiii. Nucleic acid is detected using second detection means (claim 59)

xxxiv. Nucleic acid is detected using second detection wherein second detection means is nucleic acid (claim 60 in part, 62)

xxxv. Nucleic acid is detected using second detection wherein second detection means is polypeptides (claim 60 in part)

xxxvi. Nucleic acid is detected using second detection wherein second detection means is proteins (claim 60 in part)

xxxvii. Nucleic acid is detected using second detection wherein second detection means is antibodies (claims 60 in part, 61, claim 66 in part

h. Species of detection label (claims 32 and 63 are generic)

xxxviii. Detection label is biotin (claim 64 in part, claim 66 in part),

xxxix. Detection label is a bromo-desoxyuridine label (claim 64 in part, claim 66 in part)

xl. Detection label is a digoxigenin label (claim 64 in part, claim 66 in part)

xli. Detection label is a fluorescence label (claim 69, 72)

xlii. Detection label is a UV-label

xliii. Detection label is a radio-label

xliv. Detection label is a chelator molecule (claim 64 in part, claim 66 in part).

xlv. fluorescent derivative of adenosine replacing adenosine (claim 70)

xlvi. fluorescent derivative of adenosine is ethanoadenosine (claims 70, 71)

i. Species of second detection means (claim 65 is generic)

xlvii. An antibody directed against biotin (claim 66 in part)

xlviii. An avidin (claim 66 in part)

xlix. An avidin carrying molecule (claim 66 in part)

l. A streptavidin (claim 66 in part)

li. A streptavidin carrying molecule (claim 66 in part)

lii. A Neutravidin (claim 66 in part)

liii. A Neutravidin carrying molecule (claim 66 in part)

liv. Antibody directed against bromo-desoxyuridine (claim 66 in part)

lv. Antibody directed against digoxigenin (claim 66 in part)

lvi. A radionuclide (claim 66 in part)

j. Species of binding specificity (claim 13 is generic)

lvii. binding is selective for bioactive ghrelin with a Kd of the nucleic acid from 10 pM to 1μM (claim 14).

lviii. binding excludes the binding of ghrelin different from bioactive ghrelin in the presence of a 1000-fold excess of bio-inactive ghrelin over bioactive ghrelin (claim 15)

k. Species of type of assay (claim 13 is generic)

lix. *In vitro* (claims 17 and 21 in part),

lx. *In vivo* (claims 18 and 21 in part)

l. Species of ghrelin detection methods (claim 1 generic)

lxi. Method for the detection of bioactive ghrelin (claims 18, 21 in part and 31)

lxii. Method wherein the bioactive ghrelin is specifically detected (claim 19).

lxiii. Method wherein the non-bioactive ghrelin is not detected by the nucleic acid (claim 20)

lxiv. Method wherein the non-bioactive ghrelin is detected (claim 21 in part).

m. Species of methods directed for a disease and/or a disorder (claim 31 is generic)

lxv. Diagnosis (claims 77 & 78 in part)

lxvi. Prognosis (claim 77 & 78 in part)

lxvii. Staging (claim 78 in part)

Group III invention

n. Species of type of assay (claim 22 is generic)

lxviii. *In vitro* (claim 26 in part),

lxix. *In vivo* (claim 26 in part)

Group V invention

o. Species of diseases and /or disorder (claim 28 is generic)

lxx. Obesity (claim 29 in part),

lxxi. regulation of energy balance (claim 29 in part),

lxxii. appetite (claim 29 in part),

lxxiii. body weight (claim 29 in part),

lxxiv. eating disorders (claim 29 in part),

lxxv. diabetes (claim 29 in part),

lxxvi. glucose metabolism (claim 29 in part),

lxxvii. tumor (claim 29 in part),

lxxviii. blood pressure (claim 29 in part),

lxxix. cardiovascular disease (claim 29 in part).

lxxx. disease and/or disorder is mediated by a bioactive ghrelin (claim 30).

6. Once Applicant has elected a group of invention for examination, Applicant is required, in reply to this action, to also elect a **single species from each of the categories that are** listed under the appropriate group elected, to which the claims

shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the nucleic acids claimed in a) Species of the type of nucleic acid are different and recognized as such in art; b) Species of nucleic acid based on structure have a different sequence and hence is unique molecule with unique chemical structure and function; c) Species of nucleic acid based on binding to ghrelin are mutually exclusive; d) species of interaction partners in claimed are all different biochemical classes of molecules; e) species of ghrelin claimed comprise of two mutually exclusive groups; f) species of functional nucleic acids claimed are recognized in the art as different; g) detection means specified are different as they have different requirements associated with them; h) the detection labels claimed fall into different categories of chemical compounds; i) the second detection means are also

different kinds of compounds; j) Species of binding specificity recited have different criteria associated with them; k) Species of type of assay are two mutually exclusive types of assays; l) Species of ghrelin detection methods claimed have been claimed as distinct methods and some of them are mutually exclusive; m) Species of methods directed for a disease and/or a disorder are recognized as different procedures medically and have different considerations associated with them; n) types of assays claimed are recognized in art as two different types; o) Species of diseases and /or disorder claimed are different and have been claimed as such; hence to search for each of these would be extremely burdensome.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the

above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suchira Pande whose telephone number is 571-272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Suchira Pande
Examiner
Art Unit 1637

/Teresa E Strzelecka/

Primary Examiner, Art Unit 1637

June 20, 2008